

MAIL BOX NON-FINAL RESPONSE
Attorney Docket No. 25523

36. (Withdrawn) An injection needle according to claim 35, wherein the length of the tip that is not coated by the echogenic material is about 2 mm.

37. (Withdrawn) An injection needle according to claim 23, wherein said echogenic material has thickness of at least about 5 μ m.

38. (Withdrawn) An injection needle according to claim 37, wherein said thickness is about 10 μ m.

Please add the following claims.

39. (New) A method of improving the detectability of a therapeutic device, comprising coating at least a portion of the device with a metal having a density greater than about 12 g/cc effective to increase ultrasonic detectability.

40. (New) A method of detecting a therapeutic device, comprising inserting into a subject a therapeutic device, at least a portion of which is coated with a metal having a density greater than about 12 g/cc effective to increase the device's detectability by ultrasonic waves.

REMARKS

THE PENDING CLAIMS

Claims 1-38 were pending in this application, various claims have been amended, claims 1-22 have been elected, claims 39-40 added, and claims 23-38 withdrawn from examination in this application. Accordingly, claims 1-22 and 39-40 are being examined in this application. The examiner is hereby authorized to cancel the withdrawn claims upon a finding of allowable subject matter in the remaining claims.

THE ANTICIPATION REJECTION

Claim 1 stands rejected under 35USC 102(b), allegedly because it is anticipated by US Patent 5,725,570 (the '570 patent) and US Patent 6, 287,331 (the '331 patent). This ground of rejection is most emphatically traversed.

The examiner failed to point out what information is relying on for this rejection. The applicant found one reference to a metal of density within the range of the present claims, and is discussing the prior art with reference to the patent's found statement.

US Patent 5,725,570 and 6,287,331, both to Boston Scientific, are different from the claimed invention, and fail to render the invention obvious either alone or in combination with one another. The '570 and '331 patents contain the same specification, given that the latter is a continuation of the earlier patent. The

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‘570 patent describes and claims a catheter carrying a stent, the latter being formed of a core and a sheath. The stent core is made of a metal that may have a density at least about 9.9 g/cc.

Claim 1 is directed to a method for increasing the “ultrasonic visibility” of a therapeutic device by coating it with a metal having a density greater than 12 g/cc. The ‘570 patent does not coat the core of the device with a metal of a stated density. The device additionally has a sheath, which is not a coating on the core. Moreover this sheath is made of a metal, e.g. nitinol, not coated with a metal. Accordingly, the ‘570 patent is irrelevant to the method of claim 1.

The ‘331 patent describes and claims a device formed of a metal outer member and a core therewithin formed of a different metal. However, these are separate components, not coatings of one another. Accordingly the first and second metals described in claims 6-7 and 14-15 are not coatings but are part of the outer membrane and the core. This patent is therefore also irrelevant to the claimed method.

Furthermore, a coating is to be understood as being on the outer side of the coated object. The Heath patents mention that "it is possible to put either metal on the inside or outside", but do not describe any device with heavy metal coating. It also mentions that "it is preferable to put the dense radiopaque material (e.g. tantalum) on the inside (core)...", so the Heath patents teach a heavy metal core while teaching against a heavy metal coating.

Nor do the prior art patents describe or suggest coating a device to "increase its ultrasonic visibility". That is the prior art is not concerned with detecting the presence of the device with sound waves. X-ray visibility and ultrasonic visibility involve totally different mechanisms. X-ray visibility is based on absorption or fluorescence, while ultrasonic visibility is based on reflection (echo). The two methods utilize different kinds of waves (electromagnetic waves vs. sound waves) and in different frequency ranges. Therefore, it is not obvious that means useful to increase X-ray visibility are also useful to increase ultrasonic visibility.

Although many publications have suggested means to improve ultrasonic visibility since the ‘570 patent, none has suggested a metal coating as currently claimed. Examples to the suggestions made in the prior art may be found at Sarkis et al cited by the examiner, WO00/51136 and US 5,081,9971 (both included in the applicant’s filed IDS). Apparently, skilled persons who were looking for solutions to the problem of increasing ultrasound visibility did not find it obvious to adopt the Heath disclosure for the present purpose.

¹ This patent was published after the Heath patent, but has a corresponding earlier publication from 1990: EP 0 386 936 A1.

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Moreover, noting in these patents would lead an artisan to coating the parts of the described and claimed devices with a metal coating, let alone with a metal of the characteristics required by the present claims. In view of the above remarks the examiner is invited to withdraw this rejection, or point specifically to where the relevant disclosure is within the cited patents.

THE FIRST OBVIOUSNESS REJECTION

Claim 14 stands rejected under 35USC§103(a), allegedly as being obvious over Sarkis in view of Thomas. This ground of rejection is also emphatically traversed.

Sarkis is different from the claimed invention, and fails to suggest its critical features, and Thomas is not only different but fails to cure the deficiencies of Sarkis. Neither of these publications disclose improving ultrasonic visibility by coating with a heavy metal. Therefore, this limitation of claim 2 or 15 is neither disclosed nor suggested by either reference alone or by their combination.

Furthermore, Sarkis in fact teaches away from the claimed method. Sarkis provided an improvement of ultrasound visibility by means of "an echogenic material comprising a plastic impregnated with sonically reflective particles". See, Sarkis' Abstract. Sarkis' teaching not only leads an artisan in a different direction but, in fact, provides no motivation for an artisan to add Heath's radiopaque material to Sarkis' echogenic material or to replace it therewith.

Thomas is also different from the claimed invention, and fails to render the claimed invention obvious, either alone or in combination with Sarkis. Thomas discloses a composition for preventing vasoconstriction or vasospasm. Nowhere does Thomas mention treating an aneurism, whether real or false.

Finally, the examiner states that "use of metal coatings in infusion devices is conventional in the art as evidenced by the teachings of Heath". This may at most be true, however, when such devices should be viewed by X-ray, as in the case of the Heath patents, but not when the device is to be viewed by ultrasound, as required by the presently claimed invention.

The examiner is thus invited to withdraw this rejection.

THE SECOND OBVIOUSNESS REJECTION

Claims 2-13 and 15-22 stand rejected under 35USC§1.103(a), allegedly as being obvious over Sarkis in view of Thomas, and further in view of the '570 and '331 patents. This ground of rejection is also emphatically traversed.

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Sarkis and Thomas were described above, as were the reasons for their, as well as their combination's, failure in rendering the claimed process obvious.

Similarly, the '570 and '331 patents were discussed above, as was their combination and their failure to describe or suggest the claimed method. Nothing in the '570 and/or '331 patents in fact adds to the combination of Sarkis and Thomas that would provide the missing link to the claimed invention.

When an independent claim is patentable, all claims that depend from it are patentable as well, regardless of any additional reference(s) invoked thereto. In fact, the mere number of references the examiner has needed to combine is proof of the unobviousness of the claimed invention.

This rejection is therefore believed to be moot, and the examiner is invited to withdraw it and allow claims 2-13 and 16-22 (claim 15 has been canceled).

THE CLAIM AMENDMENTS

The amendments to the claims are fully supported by the specification as filed, and by the original claims. No objectionable new matter is believed to have been introduced by this amendment.

THE PREVIOUSLY FILED I.D.S.

The examiner is cordially invited to consider of record the previously filed Information Disclosure Statement.

In view of the above remarks this application is believed to be in condition for allowance. Early notice to that effect is hereby solicited.

Respectfully submitted,
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